REMARKS/ARGUMENTS

Claims 34-37, 39-46 and 57-80 and 89-94 are in the case.

I. TELEPHONE CONFERENCE

The undersigned wishes to acknowledge a brief telephone conference conducted with the Examiner on March 19, 2010 during which the undersigned requested an interview in the case. The Examiner advised that since the case is under final rejection, it was not possible to grant a formal interview. However, the Examiner did indicate that it would be necessary to file an RCE to secure entry and consideration of the Amendment filed February 26, 2010. The present response is accompanied by an RCE. Entry and consideration of the Response dated February 26, 2010 are respectfully requested.

II. THE ADVISORY ACTION

The Advisory Action mailed March 8, 2010, asserts *inter alia* that"

> "...applicants have now added new matter to the claims by changing the claimed anhydrous form to any and all hydrated forms which the specification does not support."

This assertion is respectfully traversed. The invention of claim 34 is directed to crystalline moxifloxacin hydrochloride hydrate form A. This is characterized by an X-ray diffraction spectrum having the principal peaks as set forth in claim 34. As noted in the prior Response, Form A is not anhydrous. Paragraph [0012] of the published application specifically indicates that Form A is hydrated. The hydrate nature of Form A is also evident from the corresponding DSC (Figure 4) which has an endothermic peak

at 73.25° C, and which corresponds to the loss of the crystallization water. Such a peak is absent from the DSC of Form B (Figure 8), which is anhydrous.

The Advisory asserts that the claims extend to "to any and all hydrated forms". This is not correct. The recitation of "hydrated" means that the claims extend only to a specific hydrated form of moxifloxacin hydrochloride characterized by well defined X-ray, C-NMR and/or IR spectra, thus identifying a specific crystalline hydrated form of moxifloxacin hydrochloride. A different hydrated polymorph of moxifloxacin hydrochloride would have different spectral characteristics.

Enclosure 1 attached to the prior response is a comparison between the same PXRD spectrum contained in Grunenberg and that contained in the present application. As can be seen from the superimposed profiles, the two PXRDs differ significantly, with Grunenberg's monohydrate lacking the peaks at about 7.5 2theta and 12.5 2theta (both evidenced with a double arrow). The comparison establishes that Grunenberg's monohydrate and the present hydrated form A are two different crystalline forms.

Moreover, Brittain, *"Polymorphism of Pharmaceutical solids"*, Marcel Dekker Inc, 1999, pages 236-237 attached to the prior Response states that "the identity is established if the scattering angles of the ten strongest reflections obtained for an analyte agree to within ± 0.20 degrees with that of the reference material and if the relative intensities of these reflections do not vary by more than 20%".

According to this criterion, the strongest reflection of Form A is the peak at about 7.5 2 theta. This is missing in the diffractogram of Grunenberg's monohydrate. Consequently the basic condition for the identity of the two forms is not met.

Withdrawal of the outstanding prior art rejections and allowance of the application are respectfully requested.

Favorable action is awaited.

Respectfully submitted,

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